

MolluDab®

with 5% potassium hydroxide

Instructions For Use

For patients, parents or carers.

Please read the following package leaflet carefully because it contains important information about the use of this medical device. If you have questions, please contact your doctor or pharmacist.

MolluDab®

Solution for application to the skin for the treatment of molluscum contagiosum.

Composition

1ml MolluDab® contains 50 mg potassium hydroxide.

Other ingredient: purified water.

1 package contains 2 ml solution for

application to the skin. The bottle cap is equipped with a plastic spatula for applying the solution.

What MolluDab® is used for:

MolluDab® is used externally against molluscum contagiosum, a skin lesion caused by a virus (see also "Important information about molluscum contagiosum" overleaf).

MolluDab® causes cells which are affected by the virus to dissolve and thereby produces a defence reaction of the skin in the region affected by molluscum contagiosum.

MolluDab® is not suitable for the treatment of common warts (Verrucae). If you are not sure whether you or your child are affected by molluscum contagiosum or common warts, you should consult your doctor before using MolluDab®.

Before you use MolluDab®

MolluDab® must not be used:

- near the eyes
- on mucous membranes (for example mouth or genital region), open wounds or skin which has been scratched open
- on already inflamed molluscum bumps
- for the treatment of common warts, age warts, birthmarks as well as corns and other callus formations
- **in infants and young children under 2 years of age**
- when there is a known tendency to form excess scar tissue (hypertrophic scars, keloids)
- in persons with congenital or acquired immune deficiency (e.g. HIV infection or treatment with medications which suppress the immune system), since there is not sufficient experience with use in this patient group.

Take special care with MolluDab®

- with molluscum contagiosum during the breastfeeding period on the lactating breast. Avoid contact between the infant and the treated skin.
- in patients with atopic dermatitis (atopic eczema). MolluDab® should not be used during flare-ups of atopic dermatitis. Seek advice from your doctor if the area is affected by molluscum and dermatitis.

Using MolluDab® with other products

There are no known interactions with medicinal products. However, as a precaution, do not apply MolluDab® on to the affected area at the same time as other products.

Possible side effects

MolluDab® is well tolerated when used as directed. Like all other products for the treatment of illnesses, however, MolluDab® may also cause side effects.

Very common: Short term skin irritation,

particularly redness and slight burning at the application site. These occur immediately after the application of MolluDab® and usually subside after a few minutes. The intensity of the skin irritation depends on the sensitivity of the skin and the quantity of the applied solution. Therefore carefully note the directions for use and apply MolluDab® sparingly.

Transient inflammatory reactions with redness, itching and swelling in the region of the molluscum bump. These are intended and lead to the healing of the bump. A scab may form on the healing skin.

Uncommon: Transient reduction or increase of skin pigmentation (hypo- or hyperpigmentation).

Rare: Scar formation. The risk of scar formation is greatest when the molluscum bumps are additionally scratched open or squeezed.

Frequency not known: Pain, erosion and scaling at the application site. Eczema or rash around the molluscum or at other

body areas may occur. These skin reactions indicate that the body is fighting the virus that causes molluscums. The reactions are not thought to be specifically related to the treatment with MolluDab but more likely to the body's defense mechanism. Contact your doctor if you are unsure about the nature of any skin reaction that might occur during or after treatment.

If you observe side effects which are not listed in this package leaflet or have any concerns about the treatment, stop using MolluDab® and consult your doctor or pharmacist for further advice.

Report any safety issues to Alliance Pharmaceuticals Limited (tel.: +44(0) 1249 466 966, email: pharmacovigilance@alliancepharma.co.uk).

How to use MolluDab®

Always use MolluDab® exactly as instructed in this package leaflet (see overleaf). You should check with your doctor or pharmacist if you are not sure. See also "**Important information about safe use**" at the beginning of this leaflet.

⚠ Important information about safe use

Use carefully: MolluDab® contains potassium hydroxide solution (caustic potash) and may have a corrosive effect if used wrongly.

- **Not for oral use.**
- Keep out of the reach and sight of children. Keep the bottle out of their reach, also during use.
- Do not use MolluDab® in infants and young children under 2 years of age.
- Avoid all contact with the eyes. Wash your hands after every use.

If MolluDab® accidentally enters the eye, rinse immediately for 15 minutes with large amounts of water and seek medical advice. See a doctor immediately and show him/her this package leaflet.

- Ensure that the solution does not come into contact with healthy skin or mucous membranes in order to avoid irritation. Allow the solution to dry thoroughly in order to avoid spreading it to healthy skin. **Immediately rinse**

away solution spilled on skin and mucous membranes with plenty of running water for 15 minutes.

- **If swallowed:** Rinse mouth, drink plenty of water. DO NOT induce vomiting. Immediately call a doctor.
- In case of overdose or excessive frequent use, painful inflammation of the skin may occur. Therefore note the directions for use "How to use MolluDab®".
- Do not allow the solution to come into contact with clothing, textiles or tablecloths.
- If MolluDab® should be spilled, carefully soak the liquid with an absorbent paper towel and immediately wash the affected area with plenty of water.
- If the spatula gets stuck in the mouth of the bottle, swap the product at the pharmacy you obtained it from. Do not try to get the spatula out of the mouth of the bottle (risk of caustic burns).

Dosage

Twice daily, use the spatula to apply a **small** quantity of MolluDab® **precisely** onto the molluscum bumps, and allow the solution to **dry**.

The custom-built spatula ensures that only a very small but sufficient amount of the solution is applied. This helps protecting the healthy skin around the bump.

How to use MolluDab® correctly

1. Do this before first use

- Write the opening date on the carton and always check this date before use. MolluDab® should be used within 4 weeks after it is first opened.
- Ensure MolluDab® is used in well lit conditions.

2. Wet the spatula with MolluDab®

- **Always place MolluDab® on a firm**



and level surface out of the reach of children.

- The box can be used as a stand: press in the perforation and place the bottle in the resulting opening.
- Open the child safe closure (push and simultaneously turn to the left).
- The bottle has a protective funnel with a small plastic tube. When pulling out the spatula excess liquid is stripped off.

3. Apply MolluDab® to the molluscum contagiosum

- Dab all molluscum bumps with the **flat side** of the spatula and allow the solution to dry. After 1-3 bumps, you should wet the spatula with MolluDab® again. If no droplet (the size of a grain of sand) can be seen on the molluscum bump, please wet the spatula again and dab the bump again.



- After use, screw the lid with the spatula on again.
- Always store MolluDab® tightly closed and out of the reach and sight of children.

4. Repeat the application daily

- Apply MolluDab® as described in steps 2 and 3 **twice daily**; it is best to do this in the morning and evening.



5. End of use

- Stop using the product as soon as an inflammation appears because this indicates that a molluscum bump is healing. The inflammation is recognisable by redness which lasts for at least 12 hours.
- Stop using the product after 14 days, even if no inflammation has occurred. In this case, consult your doctor or pharmacist for further advice.



6. Wait for the molluscum lesions to heal

- The inflammation indicates that your body is fighting the molluscum bumps. Now it is time to be patient and wait for the bumps to heal. Once inflamed, healing usually takes between 1 and 4 weeks. MolluDab® must not be used on inflamed bumps. MolluDab® may still be applied to any bumps that are not inflamed and new bumps that may appear.

How to store MolluDab®

Keep MolluDab® out of the reach and sight of children.

Store bottle tightly closed.

The solution has a shelf life of 4 weeks after first being opened.

Mark the opening date on the carton.

The expiry date is printed on the carton and on the bottle.

Do not use this product after this date.

Date of revision of the text:

May 2021.



Important information about molluscum contagiosum

What causes molluscum contagiosum?

Molluscum contagiosum is a contagious disorder of the outer skin layer (epidermis) which is caused by a virus (molluscum contagiosum virus). The interior of the molluscum bump contains a whitish mass which contains numerous contagious viruses. Therefore, do not squeeze the bumps yourself and avoid scratching them open. This may otherwise cause a scar or spread the illness to other skin areas.

Common warts, condyloma, tassel warts, flat warts, foot sole or spur warts (Verrucae), on the other hand, are caused by other virus types, so called papilloma viruses. Therefore, molluscum contagiosum and common warts are two completely different disorders.

How are molluscum contagiosum transmitted?

The transmission of molluscum contagiosum generally takes place via direct contact from one person to another. Virus-containing materials from a molluscum bump enter the upper skin layers through small skin injuries (scratches, etc.) and produce a new lesion within 2 to 7 weeks. Much less often, the viruses are transmitted via jointly used clothing, towels and handkerchiefs.

Does everyone get molluscum contagiosum?

Any person can get this disease. Molluscum contagiosum are often found in children and adolescents as well as in persons who suffer from atopic dermatitis (atopic eczema). Persons whose immune system is severely weakened due to a severe illness or treatment also have molluscum contagiosum more frequently.

What hygienic measures should you take into account?

If possible, avoid scratching the existing molluscum bumps and do not squeeze them so that you do not transmit the infection to other body regions or other persons. Do not share washcloths, towels or bath sponges with other persons. Children with molluscum contagiosum should not bathe together with other children.

Does molluscum contagiosum always have to be treated?

Molluscum bumps are a harmless disorder and if you are patient, they will usually disappear on their own. However this can take months. In persons who continually reinfect themselves by scratching, it may take as long as one or two years. Molluscum lesions can become a particular nuisance in persons suffering from atopic dermatitis, since they occur in

large numbers on the diseased skin. The bumps are also regarded as unsightly, especially if they occur on the face.

ALLIANCE

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INFECTOPHARM

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